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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,389	06/09/2006	Young Hoon Park	3884-0128PUS1	3879

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EXAMINER

ARIANI, KADE

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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04/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/582,389	Applicant(s) PARK ET AL.	
	Examiner KADE ARIANI	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/2006 and 3/21/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A reference to any prior application to which applicant is claiming priority must be inserted as the first sentence of the specification.

Claims 1-4 are pending in this application and were examined on their merits.

Claim Objection

Claim 1 is objected to because of the following informalities:

In claim 1 delete "of" in the recitation "characterized of" and insert --by--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1651

The invention appears to employ a strain of *lactobacillus paracasei*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 5 lines 12-14 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

Art Unit: 1651

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code

Art Unit: 1651

and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter.

Claim 1 is directed to a strain of "*lactobacillus paracasei*" a naturally occurring lactic acid bacteria and not a "manufacture". The claims do not require any physical transformation of the *lactobacillus paracasei*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al. (Acta Biotechnol. 1994, Vol. 14, No.4, p.367-378).

Claim 1 is drawn to a strain of *lactobacillus paracasei* characterized by lactic acid production capacity and high growth rate.

Richter et al. disclose a *lactobacillus paracasei* strain with the ability to produce high amount of lactic acid and growth (Abstract and p. 371 2nd paragraph).

Richter et al. therefore clearly anticipate the claimed strain.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1651

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al. (Acta Biotechnol. 1994, Vol. 14, No.4, p.367-378). In view of Carlson et al. (US patent No. 6,475,759 B1), and further in view of Alm L. (J Dairy Sci, 1982, Vol. 65, p. 515-520).

Claims 1-4 are drawn to a strain of *lactobacillus paracasei* characterized by lactic acid production capacity, a method for producing lactic acid with high concentration by cultivating the strain *lactobacillus paracasei*, in a medium that comprises 160-180 g/L glucose, 15 g/L of yeast extract, and 7-15 g/L of peptone, the production ratio of D-lactic acid and L-lactic acid is adjusted by varying the cultivation temperature in a range of 33 -41°C, and the comprises corn steep powder in replacement of yeast extract.

Richter et al. teach a strain of *lactobacillus paracasei* characterized by high lactic acid production capacity, and a method for producing lactic acid by cultivating the strain *lactobacillus paracasei*, in MRS-glucose medium and using sugar concentration of 60 g/kg to 115 g/kg, 10 g/kg of yeast extract, and 20g/kg of peptone (p.368 3rd paragraph lines 2 and 5, and p.367 1st paragraph line 9), cultivation temperature in a range of 33 - 41°C (p.369 1st paragraph line 6).

Richter et al. do not teach 160-180-g/L glucose, 15 g/L of yeast extract, and 7-15 g/L of peptone, and corn steep powder in replacement of yeast extract. However, Alm teaches the formation of lactic acid isomers (D and L) depends upon the type of microorganism, substrate composition, temperature, pH, time of the incubation, storage temperature (see p.515 1st column, Introduction 2nd paragraph). Therefore, a person of

Art Unit: 1651

ordinary skill in the art at the time the invention was made would have realized that concentration of glucose, peptone and yeast extract in the medium could have been adjusted and optimized in order to increase the yield of lactic acid.

Moreover, Carlson et al. teach using corn steep water and steep water dry solids to produce lactate (or lactic acid) (column 6 lines 40-45). Carlson et al. teach the supplementing MRS medium with corn steep water to provide nitrogen and additional carbohydrates likes glucose or fructose (column 6 lines 49-52).

Therefore, a person of ordinary skill in the art at the time the invention was made could have been motivated to combine the prior art teachings and to substitute yeast extract with corn steep powder as taught by Carlson et al. in the method of Richter et al. to provide a method for producing lactic acid with predictable results of producing lactic acid. Because substitution of one known nitrogen source (yeast extract) wit another known nitrogen source (corn steep powder) would have yielded predictable results to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651